

Remarks

Claims 1-23 are pending in the present application. Claims 1-19 are rejected and claims 20-23 are withdrawn. Applicants gratefully acknowledge the Examiner's acceptance of the amended abstract as well as withdrawal of rejections of record under 35 USC §112, ¶2 and §103(a). By the present amendment, claim 1 is amended and claim 14 is cancelled.

Rejections Pursuant to 35 U.S.C. §102(b)

In the Office Action, claims 1-5 and 7-14 are rejected under 35 U.S.C. §102(b) as being anticipated by Ullman (U.S. Patent No. 5,445,944).

Claim 14 is cancelled herein and its subject matter has been incorporated into amended claim 1, which now recites a method for detecting an analyte by a redox reaction and a fluorimetric determination, comprising contacting a sample containing the analyte with a detection reagent. The detection reagent contains a compound of the general formula Q – F as a fluorimetric redox indicator, wherein Q is a quencher group and F is a fluorophore group. The detection reagent additionally contains an enzyme and optionally a coenzyme for reducing or oxidizing the analyte.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Ullman describes a method for determining peroxidatively active substances, which method comprises contacting a sample containing the analyte with a hydroperoxide, a hydrogen donor and a compound of the general formula F-L-Q, wherein F is a fluorescer capable of producing a signal, Q is a quencher capable of quenching the signal when linked to F, and L is a bond or a linking group having a bond. More specifically, the method comprises oxidizing a hydrogen donor (such as a benzidine) by reacting the hydrogen donor with a hydroperoxide and a peroxidatively active substance (such as a

peroxidase), the oxidized hydrogen donor causing cleavage of the compounds of the formula F-L-Q. By cleaving the bond between F and Q, the quencher activity of the signal modulating group Q is reduced, thus leading to an increase in fluorescence of the fluorescer group F.

Also in the Office Action, claims 1-3, 5 and 8-14 are rejected under §102(b) as being anticipated by Lee (U.S. Patent No. 5,795,729). Lee describes a method for fluorometrically detecting an analyte in a sample using a probe, the probe comprising a fluorescent reporter molecule and a quencher molecule, wherein the quencher molecule is converted by the analyte from a first state which is able to quench the fluorescence of the reporter molecule, to a second state which has a reduced ability to quench the reporter molecule. This change in fluorescence intensity of the reporter molecule can be used for indirectly determining the analyte.

Neither Ullman nor Lee describe the subject matter of amended claim 1. More specifically, neither patent reference teaches nor suggests contacting a sample containing an analyte with a detection reagent, which detection reagent contains an enzyme and optionally a coenzyme for reducing or oxidizing the analyte. In light of the present amendment, Ullman and Lee cannot be relied upon in support of the instant rejections. Claims 2-13 and 15-19 contain all of the limitations of the base claim from which they depend. Accordingly, applicants respectfully request the rejection be withdrawn.

Rejections Pursuant to 35 U.S.C. §103(a)

Also in the Office Action, claims 6 and 15-19 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ullman. As stated in the Office Action, claim 6 differs from Ullman in that the listed quenchers are not specifically described, and the analytes in claim 15 are not shown by Ullman. However, in support of the instant rejection, it is asserted that it would have been obvious to one of ordinary skill in the art

at the time the invention was made to select any known quenchers for their known function in view of Ullman who describes a number of quenchers and that any known quenchers can be employed – no unexpected results are seen. Moreover, regarding the analytes in claim 15, it is asserted Ullman describes an assay that determines peroxidatively related or active substances broadly, and all the analytes in claim 15 can be determined in a reaction where peroxide is generated and determined.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. MPEP 2143 (*citing In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

Claim 6 depends from claim 1 and, as noted above, Ullman does not teach or suggest the subject matter of amended claim 1 – contacting a sample containing an analyte with a detection reagent, which detection reagent contains an enzyme and optionally a coenzyme for reducing or oxidizing the analyte.

In addition, with respect to claim 15, Ullman generally requires the use of a hydroperoxide for determining the analyte and results in cleavage of the compounds referred to as F-L-Q. In contrast thereto, such use of a hydroperoxide is to be completely avoided according to the present invention which allows oxygen-independent detection of analytes such as glucose (cf. pg. 2, para. [0006] of the application). Moreover, the method according to the present invention does not require the compounds of formula F-Q to be cleaved for being fluorimetrically detectable. Thus, a person skilled in the art would not have had the slightest motivation to consider the


Ullman reference. For these reasons and in light of the amendment made herein, Ullman cannot be relied upon in support of the instant rejection. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. MPEP 2143.03 (*citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Accordingly, applicants respectfully request that the rejection be withdrawn.

Applicants note the remaining prior art cited in the Official Action (U.S. Patent Pub. No. 2003/0186349 A1 by Makings et al.). As that additional art is not applied by the Examiner against the claims of this application, applicants are not providing any comments concerning the same at this time.

Conclusion

Applicants have filed a complete response to the outstanding Office Action and respectfully submit that, in view of the above amendments and remarks, the application is in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,
ROCHE DIAGNOSTICS OPERATIONS, INC.

By 

Brian L. Smiler
Registration No. 46,458

9115 Hague Rd.
Indianapolis, IN 46250-0416
Telephone: (317) 521-3295
Facsimile: (317) 521-2883
E-mail: brian.smiler@roche.com

BLS/